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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/086,653	02/27/2002	Philipp Lang	6750-0001.20	8290
36806	7590	03/02/2004	EXAMINER	
IMAGING THERAPEUTICS, INC. C/O ROBBINS & PASTERNAK 1731 EMBARCADERO ROAD SUITE 230 PALO ALTO, CA 94304-3303			THOMAS, COURTNEY D	
			ART UNIT	PAPER NUMBER
			2882	
DATE MAILED: 03/02/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/086,653	LANG, PHILIPP	

Examiner	Art Unit	
Courtney Thomas	2882	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 27 February 2002.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-30 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1-30 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on 27 February 2002 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____ .
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>12/26/02; 2/19/03</u> .	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
	6) <input checked="" type="checkbox"/> Other: <u>3) continued - 10/17/03</u> .

DETAILED ACTION

Drawings

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore,
2. a) a wedge shaped calibration phantom having a length (L) and varying thickness (T) along the length (claim 1),
3. b) the thickness of the calibration varies linearly along the length (claim 6),
4. c) the calibration phantom varies non-linearly along the length (claim 7),
5. d) a method of generating a density calibration curve (recited in claims 8-15 and 16-18)
6. e) a method of determining bone mineral density of an X-ray image (as recited in claims 19-24) and
7. f) a kit comprising a wedge calibration phantom, an X-ray imaging assembly and computer programs as recited in claims 27-30, must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Specification

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without

underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC (See 37 CFR 1.52(e)(5) and MPEP 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text are permitted to be submitted on compact discs.) or
REFERENCE TO A "MICROFICHE APPENDIX" (See MPEP § 608.05(a). "Microfiche Appendices" were accepted by the Office until March 1, 2001.)
- (e) BACKGROUND OF THE INVENTION.
 - (1) Field of the Invention.
 - (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (f) BRIEF SUMMARY OF THE INVENTION.
- (g) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
- (h) DETAILED DESCRIPTION OF THE INVENTION.
- (i) CLAIM OR CLAIMS (commencing on a separate sheet).
- (j) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
- (k) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

Claim Objections

8. Claims 8, 9, 16, 19-24, 26 and 28-30 are objected to because of the following informalities:
9. Examiner suggests that claim 8 be re-written to include a step (c), as in the following: "c) generating a calibration curve from data collected in step (b), that describes the relationship between measured attenuation and material thickness."
10. Claim 9 recites: "... generating an expected calibration curve." It is unclear what the "expected calibration curve" relates to (i.e. a particular phantom being used; the structure under

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analysis, etc.) Examiner notes that the claim, as written is ambiguous. Claims 10-15, by virtue of their dependency, suffer from this inherited deficiency.

11. Examiner suggests that claim 16 be re-written as follows: "... measuring attenuation at a multitude of points in the X-ray image [of the] including the calibration phantom; ..."

12. Examiner suggests that claims 19-24 be re-written as follows: "... b) comparing attenuation information from the X-ray image of a subject's anatomical structure to the generated calibration curve and c) determining the bone mineral density of the subject." Examiner notes that claims 19-24 relate to various calibration curves.

13. Claim 26 recites: ... "said comparing." Examiner notes that there is no antecedent basis for this term.

14. Claim 28 recites: "A method of diagnosing osteoporosis comprising the step of analyzing an X-ray image obtained by the method of claim 1 (emphasis added)." Examiner notes that claim 1 is directed to an apparatus. Claim 28 is therefore considered ambiguous. Claims 29 and 30, by virtue of their dependency, suffer from this inherited deficiency.

15. Claim 29 recites a method of treating osteoporosis including the step of administering a suitable treatment. Examiner notes that the disclosure is silent as to what constitutes "suitable treatment."

16. Appropriate correction is required.

Claim Rejections - 35 USC § 112

17. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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18. Claims 8 and 9 and dependent claims 10-13, 25 and 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In particular, claims 8 and 9 recite a step of: "providing an assembly according to claim 1 to produce an X-ray image of an anatomical structure and measuring attenuation at a multitude of points in the X-ray image of the calibration phantom ..." It is unclear how the imaging of an anatomical structure results in the production of an X-ray image of a calibration phantom. Examiner concludes that the claim as written contains missing essential steps necessary for understanding the claimed methodology. See claim 16 for a comparative analysis. Claims 10-13, 25 and 26, by virtue of their dependency, suffer from the above noted deficiency.

Double Patenting

19. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

20. Claims 1-30 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-30 of copending Application No. 10/225363. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

21. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed.

Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

22. Claims 1-7 and 27 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 32-43 and 47 of copending Application No. 09/942528 in view of Arnold (U.S. Patent 5,335,260). Although the conflicting claims are not identical, they are not patentably distinct from each other because Application No. 09/942528 claims **a**) an X-ray assembly for determining bone mineral density comprising an X-ray film holder, X-ray film and a calibration phantom and **b**) a kit comprising a calibration phantom with integrated geometric patterns, an X-ray imaging assembly and computer programs, wherein the computer programs analyze and assess bone mineral density. Copending Application does not explicitly claim a wedge-shaped calibration phantom, having a length and a varying thickness along the length. Arnold (U.S. Patent 5,335,260) teaches the conventional use of a wedge-shaped calibration phantom (see Fig. 1 of this reference) in X-ray imaging systems which serves as a means for quality control testing of X-ray beam properties and the quantification of bone mineral density due to radiation attenuation characteristics apparent in obtained radiation images. It would have been obvious to incorporate a wedge-shaped calibration phantom into the X-ray assembly and kit of Application No. 09/942528. One would have been motivated to make such a modification for the purpose of quality control testing of X-ray beam properties in an X-ray imaging system and the quantification of bone mineral density as taught by Arnold.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

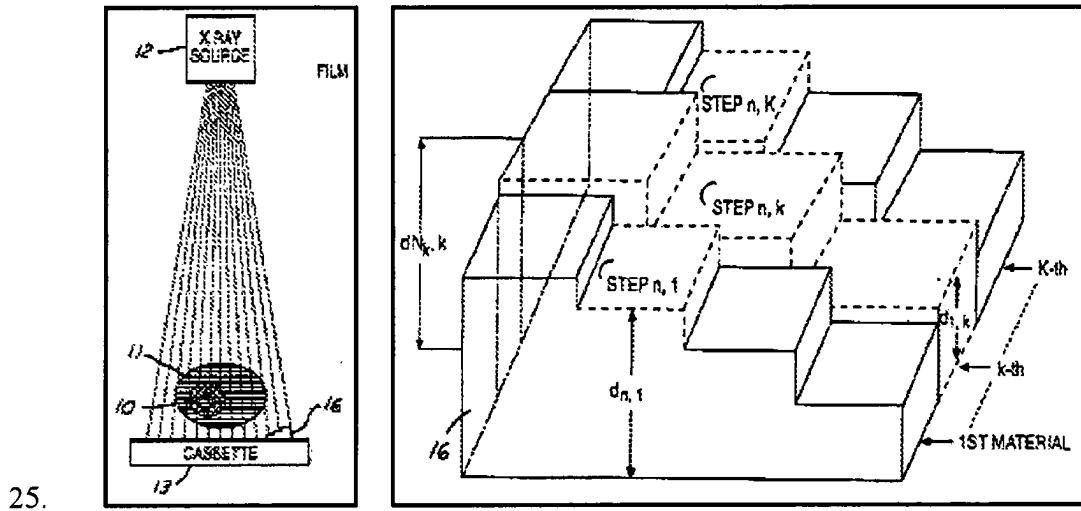
Claim Rejections - 35 USC § 102

23. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

24. Claims 1-4, 6, 7 and 27-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Chiabrera et al. (U.S. Patent 5,917,877).



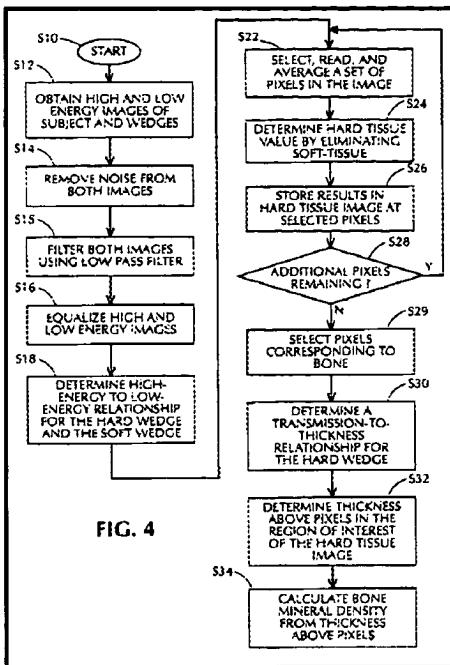
Figures 1 & 4 - U.S. Patent 5,917,877 to Chiabrera et al.

26. As per claims 1-4, 6-7 and 27, Chiabrera et al. disclose an X-ray assembly comprising an X-ray film holder (13), X-ray film ((23) - Fig. 2 – not shown above) a calibration phantom (16), an x-ray imaging assembly and computer programs, wherein said computer programs analyze and assess bone mineral density (see Figs. 1 &4 above; abstract and respective portions of the specification); wherein the calibration phantom (16) projects free of bone tissue and is

attached to the X-ray film holder or a detector system; and wherein the calibration phantom varies linearly and non-linearly along the length (see Fig. 4, above).

27. **As per claims 28-30,** Chiabrera et al. disclose a method of diagnosing osteoporosis comprising the step of analyzing an X-ray image and administering suitable treatment (column 10, lines 47-62).

28. Claims 8, 9, 11, 13, 14-16, 18-20, 23 and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Schick et al. (U.S. Patent 5,852,647).



29.

In step S30, a transmission-to-thickness function is created from the hard tissue reference data. While either the high-energy or the low-energy image may be used, the low-energy image is preferred. In addition, when the hard tissue reference includes a stepped wedge, the stepped wedge is preferred for creating this function. This function is created by reading pixels at different steps on the wedge from known locations in the image. The pixels in each step are averaged to obtain an average pixel intensity for each step. A curve fit is then performed using the average pixel intensity at each step as the 'x' value and the step height as the 'y' values. Fitting a quadratic curve to the data is preferred. Preferably, a look-up table is created based on the transmission-to-thickness function. The look-up table receives transmission (intensity) as an input and outputs thickness. An equivalent characteristic that is related to thickness (such as mass) may be used in place of thickness. When the hard tissue reference does not include a stepped wedge, data points from various heights along the hard linear wedge may be used instead.

30.

Next, in step S32, the thickness of hard tissue above each pixel of bone in the hard tissue image is determined using the hard tissue image and the transmission-to-thickness look-up table (or function). The thickness for each pixel of bone is then averaged, the average is normalized to account for the area of a pixel, and the bone mineral density (BMD) is computed in Step S34 by multiplying the average thickness by the density of the hard tissue reference material (e.g., aluminum). The BMD is measured in units of mass per area, preferably in mg per square mm. The BMD may be converted to a t-score or a z-score that describes the degree of osteoporosis using well known techniques.

65

Figure 4 & column 7, lines 34-65 – U.S. Patent 5,852,647 to Schick et al.

31. As per claims 8, 9, 11, 13, 14-16, 18-20, 23 and 24, Schick et al. disclose a method comprising the steps of a) providing an X-ray assembly comprising an X-ray film holder, X-ray film (24), and a calibration phantom (12-14), having a length (L) and a varying thickness (T) along the length and b) measuring attenuation at a multitude of points in the X-ray image of the calibration phantom wherein each point is at a known distance from the selected part of the

phantom, thereby generating a calibration curve that describes the relationship between the measured attenuation and material thickness (Fig. 4; column 5, line 47 to column 7, line 65).

Claim Rejections - 35 USC § 103

32. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

33. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chiabrera et al. (U.S. Patent 5,917,877).

34. As per claim 5, Chiabrera et al. do not explicitly disclose an X-ray assembly configured as a dental X-ray assembly.

35. It would have been obvious to modify the apparatus of Chiabrera et al. such that it was configured as a dental X-ray assembly. One would have been motivated to make such a modification in order to perform a non-invasive quantitative radiographic evaluation of a particular portion of a patient's anatomy, such as a patient's teeth and mandible structure as suggested by Chiabrera et al. (column 10, lines 47-62).

36. Claims 10, 12, 17, 21, 22, and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schick et al. (U.S. Patent 5,852,647).

37. As per claims 10, 12, 17, 21, 22, and 25, Schick et al. do not explicitly disclose a method comprising the step of translating the calibration curve (function) describing thickness into a curve describing calcium concentration.

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38. Schick et al. teach that an equivalent characteristic related to thickness may be used to describe the relationship between radiation transmission and thickness (column 7, lines 49-50).

39. It would have been obvious to modify the method of Schick et al. such that it incorporated the step of translating a calibration curve (function) describing thickness into a curve describing calcium concentration. One would have been motivated to make such a modification for the purpose of relating radiation transmission characteristics with an associated determinant such as mass as suggested by Schick et al. (column 7, lines 49-50).

Conclusion

40. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

41. U.S. Patent 4,400,827 to Spears and U.S. Patent 5,687,210 to Maitrejean et al. disclose the use of wedge shaped calibration phantoms in radiographic systems.

42. U.S. Patent 6,377,653 to Lee et al. discloses a method for determining bone mineral density using a calibration phantom.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Courtney Thomas whose telephone number is (571) 272-2496. The examiner can normally be reached on M - F (9 am - 5 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ed Glick can be reached on (571) 272 2490. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CT
Courtney Thomas


EDWARD J. GLICK
PERVISOORY PATENT EXAMINER